SCHILLER AG
Altgasse 68, Postfach
CH 6341 Baar
Tel.: +41 (41) 766 42 42
Fax: +41 (41) 761 08 80

MWST Nr. 212858
e mail: sales@schiller.ch
buying@schiller.ch
http://www.schiller.ch

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SCHILLER
SWITZERLAND

APR 1 4 2004

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850 USA

14. of May 03

FDA/CDRH/ODE/PM00
2003 MAY 19 A 11:5

Pre-market Notification Letter, 510 (k) Notification

Dear Documentation Control Clerk:

In accordance with Section 510 (k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR 807, this pre-market notification is being submitted prior to the date when SCHILLER AG, Switzerland, proposes to introduce into interstate commerce for commercial distribution of a new device CARDIOVIT AT-102

1.	Trade Names:	CARDIOVIT AT-102
2.	Common Name:	System, ECG, Analysis Product code: 74 LOS
3.	Address of Manufacturing Facility:	SCHILLER AG, Switzerland Altgasse 68 CH-6341 Baar
4.	Classification:	Class II
5.	Reason for Premarket Notification:	New Device
6.	Substantially Equivalent Devices:	CARDIOVIT AT-1C K953396
7.	Substantial Equivalence:	For all technical specifications, substantial equivalence is claimed with the SCHILLER device, CARDIOVIT AT-1C (K953396)

5K 14005

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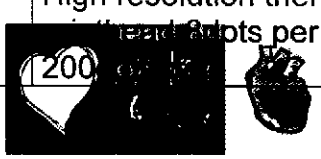
8. ECG measurement: Common Standards for Quantitative Electrocardiograph (CSE), multi lead atlas measurement results

9. ECG interpretation: CSE study
Detection of acute myocardial infarcation
a) performance verified by enzyme evolvement (PREMIS study)
b) performance verified by Cardiologists (Boehringer Ingelheim Study)

10. Safety Standards: EN 60601-1 (Safety), EN 60601-1-2 (EMC), IEC 601-1-4 (Software Quality)

11. Table of Comparison to Legally Marketed Device(s):
(Predicate device CARDIOVIT AT-1C (K953396)

	AT-1C K953396	CARDIOVIT AT-102
Dimensions:	290x210x69mm	380x328x100mm
Weight:	2.9 kg	5.0 kg
Environmental Conditions:		
Operating temperature	+10° - 40° C	same
Storage temperature	-10° - +50° C	same
Relative humidity	25% - 95% (non condensing	same
Leads:	Standard / Cabrera	same
Battery capacity:	2 hrs of normal use	same
Frequency range of digital recorder:	0 to 150Hz	same
Control panel	Pad keys, LED indications	Alphanumerics, LCD Display
Myogram Filter	25Hz or 35Hz programmable	same
Paper speed	5/25/50mm/s (direct)	5/10/25/50mm/s direct
Printing process	High resolution thermal [illegible] 8dots per mm 200	same



	inch(amplitude axes) 40dots per mm / 1000 dots per inch time axes, 25mm/s	
Chart paper	Thermoreactive, Z-folded, 90mm	Thermoreactive, Z-folded, 210mm
Recording tracks	3 channels, positioned at optimal with on 80 mm / 3.2 inch automatic baseline adjustement	6 channels, positioned at optimal with on 80 mm / 3.2 inch automatic baseline adjustement
Automatic lead programs	3 channel representation of 12 simultaneously acquired standard leads	6 channel representation of 12 simultaneously acquired standard leads

Discusson of Differences:

None of the above differences (1, 2 or 3) can be considered as safety relevant differences.
We consider the submitted device to be as safe and effective as the Predicate (CARDIOVIT AT-1C) device.

M. Buetler

Markus Buetler

14.05.03

(Date)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2004

SCHILLER AG
c/o Mr. Markus Buetler
Quality Assurance and Regulatory Affairs Manager
Altgasse 68, Postfach
CH-6341 Baar
SWITZERLAND

Re: K031557
Trade Name: CARDIOVIT AT-102
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: DPS
Dated: March 19, 2004
Received: March 23, 2004

Dear Mr. Buetler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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FDA U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Indications for Use

510(k) Number (if known): K031557

Device Name: Cardiovit AT-102 / P8000Power

Indications for Use:

The AT-102 is a 12-channel, ECG Device used for the recording, analysis and evaluation of ECG recordings. Recordings made with the AT-102 can be used as a diagnostic aid for heart function and heart conditions. The AT-102 is designed for indoor use.
The device provide an optional interface to the SP-250 for pulmonary function data.

SCHILLER AG
Altgasse 68
CH-6341 Baar/Switzerland

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Prescription Use x (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031557